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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,732	04/08/2004	Yasuyuki Kawashima	11333/38	1524

7590 02/09/2007
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Chicago, IL 60610

EXAMINER

PETERSEN, CLARK D

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/821,732

Applicant(s)

KAWASHIMA, YASUYUKI

Examiner

Clark D. Petersen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-21 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 11-21 and 25-27 in the reply filed on 9 November 2006 is acknowledged.

Claims 1-10 and 22-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9 November 2006.

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119 a-d, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an

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international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the

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information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-15, 17, 19, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda et al (US Patent # 6,165,740, issued 26 Dec 2000). Fukuda et al disclose a device capable of distinguishing between *Staphylococcus* and *Bacillus* bacteria in a sample by analyzing the sample by flow cytometry. Cultured *Staphylococcus* and *Bacillus* bacteria form different sized aggregates during growth. When analyzed by flow cytometry, the aggregates reflect fluorescent light and scatter other light differently, allowing a sensor to discern between the two types of bacteria (see Abstract; see Summary of the Invention, col. 3 line 61 to col. 4 line 48; see First Embodiment, col. 6 line 25 to col. 8 line 10, as examples). Additionally the unit is equipped with an analysis capability which can diagram particle distributions in two

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dimensions, from which any required information such as slope of distribution can be measured, reading on instant claims 12-14 (see Fig. 29, for example).

Therefore the teachings of Fukuda et al are deemed to anticipate the instant claims 11-15, 17, 19, and 25-27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-21 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al (US Patent # 6,165,740, issued 26 Dec 2000) in view of Kubitschek et al (J Bacteriol, Dec 1986) and in view of Chupp et al (US Pat # 5,631,165, issued 20 May 1997). The teachings of Fukuda et al are discussed above and applied as before.

Fukuda does not expressly teach a first detector that determines size information by detecting electrical resistance.

Fukuda does not expressly teach an output part for determining reliability of data, or that outputs a warning when the control unit has determined that identifying bacteria type is difficult.

Kubitschek et al teach that a Coulter-type impedance detector can reliably detect bacterial cell volume. They measure the size determined by impedance counter versus

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the size determined by pelleting cells and measuring the pellet volume versus cell count, and determine that the relationship between actual cell size and cell size determined by Coulter impedance counter is reliably the same (see p. 1466, col. 1, paragraph 1; see Fig. 1, p. 1467, for example). Kubitschek et al conclude "the agreement between mean cell volumes measured by the two methods provides evidence that cell volumes determined with the Coulter Counter-Analyzer system are in substantial agreement with the values determined biophysically for the same cells, thereby validating the use of electronic cell sizing for measurements of bacterial volumes" (see p. 1467, col. 2, final paragraph).

Chupp et al teach that a single instrument can comprise both an impedance transducer and a optical flowcell/transducer for detecting light scattering and fluorescence (see "System Overview", col. 11, lines 35-48, for example).

Chupp et al also teach that a system can automatically determine statistical significance of the data it is collecting, and alter its actions based on its determination of statistical significance. For example, when cell counts are low, the apparatus can correct its counting time to improve statistical significance of the data. It would be obvious to include a warning system rather than alter counting times; both involve apparatus determination of statistical significance and determining a response to the determined significance (see col. 56, lines 25-27, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to arrange an apparatus comprising an optical cytometer and a Coulter impedance counter because Fukuda et al teach that cocci and bacilli can be

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differentiated by light scattering as well as determination of the volume of the aggregates they form as they grow, Kubitschek et al teach that a Coulter counter can reliably determine bacterial cell volume, and Chupp et al teach that one can combine a Coulter counter and an optical cytometer in a single apparatus.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to arrange a single apparatus for determining bacterial species by combining an impedance analyzer with an optical flow cytometer.

Conclusion

No claims are allowed.

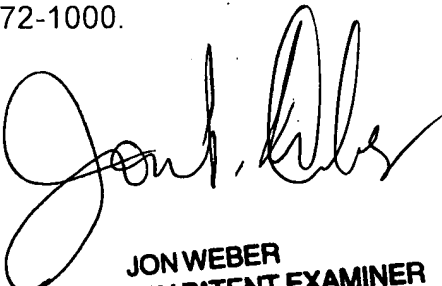
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
1/18/2006



JON WEBER
SUPERVISORY PATENT EXAMINER